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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/595,977

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Mark Ashby

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EXAMINER

MASHACK, MARK F

ART UNIT

PAPER NUMBER

3773

MAIL DATE

DELIVERY MODE

03/15/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/595,977	Applicant(s) ASHBY ET AL.	
	Examiner MARK MASHACK	Art Unit 3773	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 February 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,27,29-33,40-49,61 and 62 is/are pending in the application.
- 4a) Of the above claim(s) 29-33 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,27,40-49,61 and 62 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This office action is in response to a communication dated 2/3/2010. Claims 1, 27, 29-33, 40-49, and 59-60 have been amended. Claims 29-33 have been withdrawn.

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 2/3/2010 has been entered.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. **Claims 40-49** are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The originally filed specification does not

support the claimed limitation of “a connector disposed between the flexible disk and the hemostatic body to couple the flexible disk to the hemostatic body”.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. **Claims 1, 40-46, 61** are rejected under 35 U.S.C. 103(a) as being unpatentable over **Nash et al. (“Nash” US 5,700,277)** in view of **Hannam et al. (“Hannam” US 5,649,959)**.

Nash discloses an apparatus comprising a plug **32**; a release mechanism **30, 36** including a hemostatic material (Column 2, Lines 1-4) and a resilient extension member **36**, the resilient extension member has an aperture **62** therein and a suture **34** passing through, the resilient extension member **36** comprises a hemostatic material; the

release mechanism is capable of positioning and releasing the flexible plug intravascularly. The hemostatic material is capable of being positioned between the release mechanism and the plug (FIG 3 and 9). A connector (elements **36, or 78**) is disposed between the disk and the hemostatic body. The bottom of the hemostatic material is removably attached to the top surface of the flexible plug. The suture is secured to the resilient extension member by tying one end of the suture to itself into knot **58A**. **Nash** discloses all of the claimed limitations except for the plug being sized to circumferentially cover the blood vessel puncture site and being sufficiently flexible to conform to and seal the blood vessel puncture site. However, **Hannam** teaches of a similar apparatus comprising a plug with those properties (Column 7, Lines 34-46). It would have been obvious to modify the anchor with these properties in order to prevent injury to the vessel and prevent the release of the hemostatic vessel into the vessel.

Regarding Claims 42-43, the release mechanism **34** comprised a suture **34** which is secured to the hemostatic body **30** with knot **58**. An adhesive is an obvious variant of a knot. It would have been obvious to one of ordinary skill in the art at the time of the invention to substitute one known element for another to yield predictable results. If that is not convincing, it was well known in the art at the time of the invention to reinforce a knot with an adhesive.

7. **Claims 1, 40, 44-49, 62** are rejected under 35 U.S.C. 103(a) as being unpatentable over **Kensey et al. ("Kensey" US 5,441,517)** in view of **Hannam**.

Kensey discloses an apparatus comprising a plug **32**; a release mechanism comprising a hemostatic material **30** and a resilient extension member **704**; a connector **504** between the plug and the hemostatic body. The resilient extension member comprises a hemostatic material (Column 14, Lines 33-35), has a bore **708** having an aperture at the top, and is secured by tying a suture to itself into knot **64**. The outer surface of the member encapsulated the inner portion of the member and both comprising a hemostatic material. **Kensey** discloses all of the claimed limitations except for the plug being sized to circumferentially cover the blood vessel puncture site and being sufficiently flexible to conform to and seal the blood vessel puncture site. However, **Hannam** teaches of a similar apparatus comprising a plug with those properties (Column 7, Lines 34-46). It would have been obvious to modify the anchor with these properties in order to prevent injury to the vessel and prevent the release of the hemostatic vessel into the vessel.

8. **Claim 27** is rejected under 35 U.S.C. 103(a) as being unpatentable over **Nash** in view of **Hannam** as applied to claim 1 above, and further in view of **Haaga (US 5,254,105)**.

Nash in view of **Hannam** disclose all of the claimed limitations. Additionally, the outer surface of the hemostatic material can be considered a biocompatible dissolvable capsule. If that is not convincing, **Haaga** teaches a similar device comprising a hemostatic material encapsulated in a biocompatible dissolvable capsule (Column 1, Line 59, - Column 2, Line 8). It would have been obvious to provide this capsule of the

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device in order to provide a time-release mechanism to enhance the clot formation
(Column 1, Line 67, - Column 2, Line 5).

Response to Arguments

9. Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MARK MASHACK whose telephone number is (571)270-3861. The examiner can normally be reached on Monday-Thursday 9:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571) 272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Mark Mashack/
Examiner, Art Unit 3773

/Melanie Tyson/
Examiner, Art Unit 3773
March 12, 2010